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APPLICATION NO.	FILING DATE	FIRST NAMEO INVENTOR	ATTORNEY OOCKET NO.	CONFIRMATION NO.
09/836,705	04/17/2001	Yuki Abe	01149/HG	7090

1933 7590 02/19/2003

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EXAMINER	
KERR, KATHLEEN M	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/836,705	ABE ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. A preliminary amendment filed on April 17, 2001 and second preliminary amendment filed on October 25, 2001 have been entered. Claims 1-55 are pending in the instant Office action.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-4, 8-10, 13-17, 23-34, and 54, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 37/38, classified in class 435, subclass 252.3.

II. Claims 1, 5-7, 8, 11, 12, 18-34, and 55, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 41/42, classified in class 435, subclass 252.3.

III. Claims 35-37, drawn to polypeptides relating to SEQ ID NO: 38, classified in class 435, subclass 195.

IV. Claims 35, 38, and 39, drawn to polypeptides relating to SEQ ID NO: 42, classified in class 530, subclass 350.

V. Claims 40-43, 45, drawn to methods of producing ML-236B or pravastatin using SEQ ID NO: 37, classified in class 435, subclass 156.

VI. Claims 40-43, 45, drawn to methods of producing ML-236B or pravastatin using SEQ ID NO: 41, classified in class 435, subclass 156.

VII. Claim 44, drawn to ML-236B compound, classified in class 435, subclass 156.

VIII. Claim 46, drawn to antibodies to SEQ ID NO: 38, classified in class 530, subclass 387.1.

IX. Claim 46, drawn to antibodies to SEQ ID NO: 42, classified in class 530, subclass 387.1.

X. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 43/44, classified in class 435, subclass 252.3.

XI. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 45/46, classified in class 435, subclass 252.3.

XII. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 47/48, classified in class 435, subclass 252.3.

XIII. Claims 47-51, drawn to polynucleotides, vectors, and host cells relating to SEQ ID NOs: 49/50, classified in class 435, subclass 252.3.

XIV. Claim 52, drawn to polypeptides relating to SEQ ID NO: 44, classified in class 435, subclass 183.

XV. Claim 52, drawn to polypeptides relating to SEQ ID NO: 46, classified in class 435, subclass 183.

XVI. Claim 52, drawn to polypeptides relating to SEQ ID NO: 48, classified in class 435, subclass 190.

XVII. Claim 52, drawn to polypeptides relating to SEQ ID NO: 50, classified in class 435, subclass 190.

XVIII. Claim 53, drawn to methods of producing ML-236B using SEQ ID NOs: 43/44, classified in class 435, subclass 156.

XIX. Claim 53, drawn to methods of producing ML-236B using SEQ ID NOs: 45/46, classified in class 435, subclass 156.

XX. Claim 53, drawn to methods of producing ML-236B using SEQ ID NOs: 47/48, classified in class 435, subclass 156.

XXI. Claim 53, drawn to methods of producing ML-236B using SEQ ID NOs: 49/50, classified in class 435, subclass 156.

3. The inventions are distinct, each from the other because of the following reasons:

(DNA Groups) Groups I, II, and X-XIII are related to each other as nucleic acids encoding enzymes involved in ML-236B biosynthesis. However, these nucleic acids encode enzymes which each have distinct functional properties catalyzing unique reactions in the biosynthetic pathway of the polyketide ML-236B. Furthermore, these nucleic acids encode enzymes having distinct structural properties with varying amino acid sequence, and thus varying nucleic acid sequence, lacking any consensus among the Groups. Thus, Groups I, II and X-XIII are patentably distinct, each from the other. While these Groups of DNAs are all identically classified, to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

(Polypeptide Groups) Groups III, IV, and XIV-XVII are related polypeptides, which are involved in the biosynthetic pathway of ML-236B. These enzymes are distinct from each other

for the same reasons cited above for their encoding nucleic acids. Thus, Groups III, IV, and XIV-XVII are patentably distinct, each from the other. While these Groups of polypeptides may be identically classified (which classification may be amended as functions of the polypeptides are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

(Method Groups) The methods of Groups V, VI, and XVIII-XXI are related as methods of using distinct nucleic acids encoding biosynthetic enzymes involved in ML-236B production. The methods of each Group are distinct from every other Group for the reasons cited above for the distinctness of the nucleic acids and/or the enzymes. Thus, Groups V, VI, and XVIII-XXI are patentably distinct, each from the other.

(Antibody Groups) Groups VIII and IX are related as antibodies specific for polypeptides, which are involved in the biosynthetic pathway of ML-236B. These antibodies are distinct from each other for the same reasons cited above for their related polypeptides and their encoding nucleic acids. Thus, Groups VIII and IX are patentably distinct, each from the other. While these Groups of antibodies may be identically classified (which classification may be amended as functions of the polypeptides are noted), to search any more than one of the defined Groups would present a search burden on the Examiner based on the extensive searching and evaluation required for any one sequence in the sequence databases as well as patent and non-patent literature text-based databases.

The DNA of Groups I, II, and X-XIII are related to the enzymes of Groups III, IV, and XVII by virtue of the fact that the DNA encode the enzymes. The DNA molecule has utility for

the recombinant production of the enzyme in a host cell. Although the DNA and the enzyme are related, they are distinct inventions because the enzyme product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups I, II, and X-XIII are patentably distinct from Groups III, IV, and XVII. While the searches of DNA and related, encoded proteins are related, they are not co-extensive because each are searched in separate sequence databases (either DNA or protein commercial and patent databases) as well as in different class/subclasses. Thus, a search burden exists for the DNA and the encoded protein to be searched together.

Inventions of Groups I, II, and X-XIII are related to inventions of Groups V, VI, and XVIII-XXI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the host cells can be used for a materially different process of using that product, such as in the recombinant production of the encoded enzyme for inhibitor studies. Thus, Groups I, II, and X-XIII are patentably distinct from Groups V, VI, and XVIII-XXI. Due to the distinct class/subclasses of the instant Groups, a search of the DNA and the methods would not be co-extensive and, thus, would present a search burden on the Examiner.

Inventions of Groups I, II, and X-XIII are unrelated to Group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04,

M.P.E.P. § 808.01). In the instant case the different inventions have wholly different structures with wholly different functions – one encodes enzymes and another is a useful therapeutic compound. Thus, Groups I, II, and X-XIII are patentably distinct from Group VII. Due to the distinct class/subclasses of the instant Groups, a search of the DNA and the compound would not be co-extensive and, thus, would present a search burden on the Examiner.

Groups I, II, and X-XIII, drawn to polynucleotides, and Groups VIII-IX, drawn to antibodies, are related by virtue of the polypeptides that are encoded by the polynucleotides and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, Groups I, II, and X-XIII are patentably distinct from Groups VIII-IX. Due to the distinct class/subclasses of the instant Groups, a search of the DNA and the antibodies would not be co-extensive and, thus, would present a search burden on the Examiner.

Inventions of Groups III, IV, and XIV-XVII, drawn to polypeptides, are related to inventions of Groups V, VI, and XVIII-XXI drawn to methods, by virtue of the DNA that encodes the polypeptides and is used in the methods. However, the Groups are distinct because the polypeptides themselves are not used in the methods. Thus, Groups III, IV, and XIV-XVII are patentably distinct from Groups V, VI, and XVIII-XXI. Due to the distinct class/subclasses of the instant Groups, a search of the polypeptides and the methods would not be co-extensive and, thus, would present a search burden on the Examiner.

Inventions of Groups III, IV and XIV-XVII are unrelated to Group VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04,

M.P.E.P. § 808.01). In the instant case the different inventions have wholly different structures with wholly different functions – one are enzymes and another is a useful therapeutic compound. Thus, Groups III, IV and XIV-XVII are patentably distinct from Group VII. Due to the distinct class/subclasses of the instant Groups, a search of the DNA and the compound would not be co-extensive and, thus, would present a search burden on the Examiner.

The polypeptides of Groups III, IV, and XIV-XVII and the antibodies of Groups VIII and IX are related by virtue of being the cognate antigen (enzyme) necessary for the production of the antibody. Although the enzyme and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are functionally distinct chemical entities and because the enzymes can be used in processes materially distinct from the process to produce antibody, such as in a enzyme activity assays. Furthermore, the enzymes can be made using other and materially distinct processes from those used to make an antibody; for example, the enzymes can be made using organic synthesis while antibody production can be in vivo. Therefore, Groups III, IV, and XIV-XVII are patentably distinct from Groups VIII and IX. Due to the distinct class/subclasses of the instant Groups, a search of the polypeptides and the antibodies would not be co-extensive and, thus, would present a search burden on the Examiner.

Inventions of Groups V, VI, and XVIII-XXI and Group VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, the product can be made by another and materially different process, such as full organic synthesis. Thus, Groups V, VI, and XVIII-XXI are

patentably distinct from Group VII. Due to the distinct class/subclasses of the instant Groups, a search of the methods and the compounds would not be co-extensive and, thus, would present a search burden on the Examiner.

The methods of Groups V, VI, and XVIII-XXI are related to the antibodies of Groups VIII and IX by virtue of the DNA that encodes the protein the antibodies are specific for being the DNA used in the methods. However, the Groups are distinct because the antibodies themselves are not used in the methods. Thus, Groups V, VI, and XVIII-XXI are patentably distinct from Groups VIII and IX. Due to the distinct class/subclasses of the instant Groups, a search of the antibodies and the methods would not be co-extensive and, thus, would present a search burden on the Examiner.

Election

4. A telephone call was made to Richard Barth on February 13, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
February 13, 2003